A final order reclassifying shortwave diathermy (SWD) intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues, a preamendments Class III device, into class II, and renaming the device "nonthermal shortwave therapy" (SWT), was published on October 13, 2015. See here: https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to

While the device submitted and cleared through K091966 may serve as a valid predicate device for a new SWT device, please refer to the aforementioned final order for current regulatory requirements for this device type.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

AngioScore, Inc.
c/o Ms. Kimberley Kline
Senior Manager, Regulatory Affairs
5055 Brandin Court
Fremont, CA 94538

Re: K091966
AngioSculpt PTA Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: June 30, 2009
Received: July 1, 2009

Dear Ms. Kline:

This letter corrects our substantially equivalent letter of July 30, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

AngioScore®

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091966

Device Name: AngioSculpt® Scoring Balloon Catheter

Indications for Use:

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, and infra popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091966

5055 Brandin Court Fremont CA 94538 www.angioscore.com Toll Free: 1.877.264.4692 Phone: 1.510.933.7900 Fax: 1.510.933.7901

AngioScore®

JUL 30 2009

K091966

510(k) Summary for the AngioSculpt Scoring Balloon Catheter

1. Submitter's Name / Contact Person

Submitter: AngioScore, Inc.
5055 Brandin Court
Fremont, CA 94538

Contact Person: Kimberley Kline
Principal Regulatory Specialist
Phone: 510-933-7989
Fax: 510-933-7994

Summary Preparation Date: June 30, 2009

2. General Information

Trade Name:	AngioSculpt® PTA Scoring Balloon Catheter
Common / Usual Name:	Angioplasty catheter
Classification Name:	Percutaneous catheter
Product Codes:	DQY and LIT
Predicate Devices:	AngioSculpt® Scoring Balloon Catheter (K072225, K080151, K081220, and K082059)

3. Intended Use / Indications

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, and infra popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

4. Device Description

The AngioSculpt catheter is a standard two-lumen catheter with a scoring balloon near the distal tip. The distal end of the catheter has a conventional nylon-blend balloon with a nitinol scoring element that wraps around the balloon. The scoring element creates focal concentrations of dilating force which minimizes balloon slippage and assists with luminal expansion of stenotic arteries. The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

5. Substantial Equivalence Comparison

The AngioSculpt catheter shares the same indications for use, fundamental design, scientific technology (operating principle), functional performance, and materials as the currently marketed AngioSculpt catheter. Design verification and validation testing demonstrated adequate device performance and confirmed that no new questions of safety or effectiveness for peripheral balloon angioplasty devices were raised. The changes to the subject AngioSculpt PTA Scoring Balloon Catheter do not affect the intended use of the device, alter the fundamental scientific technology of the device, or raise new issues of safety and effectiveness. The AngioSculpt PTA Scoring Balloon Catheter is therefore, substantially equivalent to the predicate AngioSculpt catheters.